K121536

510(k) SUMMARY

SUBMITTER:

Sorin Group Italia S.r.l.
86, Via Statale 12 Nord
41037 Mirandola (MO) Italy

AUG 2 2 2012

CONTACT PERSON:

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DATE PREPARED:

May 23, 2012

DEVICE TRADE NAME:

INSPIRE 8F hollow fiber oxygenator with integrated arterial filter and hardshell venous/cardiotomy reservoir

COMMON NAMES:

Hollow Fiber Oxygenator with integrated arterial filter and hardshell venous/cardiotomy reservoir
Hollow Fiber Oxygenator with integrated arterial filter
Hardshell Venous/Cardiotomy Reservoir

CLASSIFICATION NAMES:

Cardiopulmonary Bypass Oxygenator/
Cardiopulmonary Bypass Heat Exchanger/
Cardiopulmonary Bypass Blood Reservoir/
Cardiopulmonary Bypass Defoamer/
Cardiopulmonary Bypass Arterial Line Blood Filter

PREDICATE DEVICE:

D903 AVANT 2 Ph.I.S.I.O. Adult Hollow Fiber Oxygenator with Ph.I.S.I.O. coating (K033323)

Micro 40 Ph.I.S.I.O. Adult Arterial Filter (K040184)

DEVICE DESCRIPTION:

The INSPIRE 8F consists of an oxygenator, integrated with an arterial filter and a heat exchanger (INSPIRE 8F M), and a hardshell venous/cardiotomy reservoir (INSPIRE HVR). The reservoir is connected to the gas exchange module by means of a molded fitting joint.
The INSPIRE 8F is a high efficiency microporous hollow fiber membrane oxygenator, integrated with an arterial filter and a heat exchanger, connected to a hardshell venous/cardiotomy reservoir.
The device can be operated at flow rates up to 8 liters per minute (l/min).
The hollow fiber membrane oxygenator provides oxygenation and carbon dioxide removal from venous blood or suctioned blood. The integrated heat exchanger controls

blood temperature and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The integrated arterial filter provides additional protection against air and solid emboli and the integrated hardshell reservoir collects, defoams, filters venous and suctioned blood, and can be used post-operatively for chest drainage. The INSPIRE 8F is a modified version of the currently marketed integrated oxygenator/hardshell venous cardiotomy reservoir system (D903 AVANT 2 Ph.I.S.I.O., hereinafter referred to as D903 AVANT) combined with the arterial filter (Micro 40 Ph.I.S.I.O. Adult Arterial Filter, hereinafter referred to as D734). Currently, these products are offered as separate units.

INDICATION FOR USE:
The intended use for the two elements that constitute the integrated device are:

INSPIRE 8F M: Hollow Fiber Oxygenator
The INSPIRE 8F M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. INSPIRE 8F M integrated arterial filter provides additional protection against air and solid emboli. INSPIRE 8F M is intended to be used for 6 hours or less.

INSPIRE HVR: Hardshell Venous/Cardiotomy Reservoir
INSPIRE HVR is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It collects, defoams and filters venous blood and suction blood. INSPIRE HVR can be used post-operatively for chest drainage.
INSPIRE HVR is intended to be used for 6 hours or less.

TECHNOLOGICAL CHARACTERISTICS:
The INSPIRE 8F has the same fundamental technological characteristics, principles of operation and control mechanisms as the predicate devices.
Sorin believes that the INSPIRE 8F is substantially equivalent to the D903 AVANT on the basis of operating principles and basic function. The integrated arterial filter of INSPIRE 8F is also substantially equivalent to the D734 predicate device with respect to the primary function of an arterial filter.
The INSPIRE 8F and the predicate devices share the same fundamental technological characteristics except for some modifications that do not affect the basic device function. These differences do not raise any new issues of safety and effectiveness.

The INSPIRE 8F is ethylene oxide sterilized and has a non-pyrogenic fluid path. It is for single use only.

NON CLINICAL TEST RESULTS:
Applicable tests were carried out in accordance with the requirements of ISO 10993-1 and the FDA May 1st, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing of materials.

IN VITRO TEST RESULTS:

In vitro testing was conducted in accordance with the relevant requirements of "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final Guidance for Industry and FDA Staff" issued on November 13, 2000, "Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions; Final Guidance for Industry and FDA" issued on November 29, 2000; "Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions; Final Guidance for Industry and FDA" issued on November 29, 2000; ISO 15675 "Cardiovascular implants and artificial organs — Cardiopulmonary bypass systems — Arterial blood line filters"; ISO 15674, "Cardiovascular implants and artificial organs — Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags"; and ISO 7199 "Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)".In vitro testing was conducted to demonstrate predicate devices substantial equivalency and compliance to safety and effectiveness requirements.

The following table lists the performance and physical/mechanical integrity tests conducted to demonstrate compliance to the product's performance specifications. The INSPIRE 8F successfully met all acceptance criteria for each test.

TEST	TEST CLASSIFICATION	TEST TITLE
1	Physical/Mechanical	Oxygenating module structural integrity
2	Physical/Mechanical	Reservoir structural integrity
3	Physical/Mechanical	Oxygenating module blood, water, gas pathway integrity
4	Physical/Mechanical	Reservoir blood pathway integrity
5	Functional/Performance	Oxygenating module blood volume capacity
6	Functional/Performance	Reservoir blood rest volume
7	Functional/Performance	Oxygenating module gas transfer performance/blood side pressure drop
8	Functional/Performance	Oxygenating module heat exchange performance/water side pressure drop
9	Functional/Performance	Oxygenating module air handling capability
10	Functional/Performance	Reservoir air handling
11	Functional/Performance	Reservoir break-through time and volume
12	Functional/Performance	Reservoir defoaming efficiency
13	Functional/Performance	Reservoir dynamic priming volume / Hold-up
14	Functional/Performance	Oxygenating module filtration efficiency
15	Functional/Performance	Reservoir filtration efficiency - venous section

TEST	TEST CLASSIFICATION	TEST TITLE
16	Functional/Performance	Reservoir filtration efficiency - cardiotomy section
17	Functional/Performance	Reservoir flow rate capacity
18	Functional/Performance	Reservoir pressure drop
19	Functional/Performance	Integrated device hemolysis
20	Functional/Performance	Integrated device blood compatibility
21	Functional/Performance	Oxygenating module leaching of coating
22	Functional/Performance	Reservoir leaching of coating
23	Functional/Performance	Integrated device flaking of coating
24	Functional/Performance	Oxygenating module uniformity of coating
25	Functional/Performance	Reservoir uniformity of coating

CONCLUSIONS:
The results of *in vitro* studies demonstrate that the INSPIRE 8F performs in a manner substantially equivalent to the D903 AVANT predicate device with respect to the relevant functional parameters. Also, the INSPIRE 8F performs in a manner substantially equivalent to the D734 predicate device, with respect to the filtering and air handling performances. Test results of this study demonstrate the INSPIRE 8F is equivalent to the predicate devices with respect to device function.
Additional testing has also demonstrated the effectiveness of production techniques to assure that the device is sterile and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 22 2012

Sorin Group USA, Inc.
c/o Mr. Scott Light
Regulatory Affairs Manager
14401 W. 65th Way
Arvada, CO 80004

Re: K121536
Trade/Device Name: Inspire 8F Hollow Fiber Oxygenator with Integrated Arterial Filter and Hardshell Venous/Cardiotomy Reservoir
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: May 23, 2012
Received: May 24, 2012

Dear Mr. Light:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

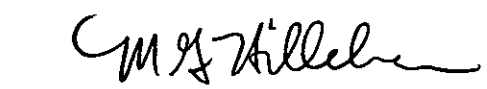
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use:

INSPIRE 8F M: Hollow Fiber Oxygenator

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INSPIRE HVR: Hardshell Venous/Cardiotomy Reservoir

INSPIRE HVR is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It collects, defoams and filters venous blood and suction blood. INSPIRE HVR can be used post-operatively for chest drainage. INSPIRE HVR is intended to be used for 6 hours or less.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121536